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Sterilization Devices In Infection Control: Effectiveness, Prioritization, And Clinical Impact In Healthcare Settings

Faisal Mutaib Al-Otaibi[1], Mohammed Nasser Ali Alhariqi[2], Mohmmed Naji Alsaedi [3], Othman Ibrahim Essa Ageeli[4], Muteb Ali Ali Alsharif[5], Nawaf Nasser Saad Alotaibi[6], Hadi Hussain Saeed Al Doghman[7], Mariam Abdullah Alateyah[8], Khalifa Hassan Alali[9], li Ibrahim Aljaroudi[10], Moqdad Abduazim Alsaffar[11], Mohammed Ali Abdullah Almuallim [12], Samah Naji Alalawi[13], Salem Awadh Saleh Alsurur[14], Layla Hussein Mohammed Awaji [15]

[1]Biomedical Technician, Marat General Hospital, Riyadh Third Health Cluster, Riyadh, Kingdom of Saudi Arabia.
[2]X-ray Technician, Hawtat Bani Tamim Hospital, Kingdom of Saudi Arabia.
[3]Pharmacy Technician, Heart Surgery Center, City Health Complex, Kingdom of Saudi Arabia
[4]Lab specialist, Farasan General Hospital, Jazan Cluster, Kingdom of Saudi Arabia.
[5]Physiotherapy Technician, King Khalid Hospital in Najran, Najran Health Cluster, Kingdom of Saudi Arabia.
[6]Nursing Specialist, Prince Salman Bin Mohammed Hospital, Ministry of Health, Kingdom of Saudi Arabia.
[7]Nurse, King Khalid Hospital, Najran Health Cluster, Kingdom of Saudi Arabia.
[8]Health administration specialist, Al-Ahsa healtH Cluster, Kingdom of Saudi Arabia.
[9]Dental Hygiene Technician, PHC Alhasa, Kingdom of Saudi Arabia. Khalifaa@moh.gov.sa
[10]Public Health Specialist, Eradah Complex and Mental Health – Dammam, Kingdom of Saudi Arabia.
[11]Epidemiology Technician, Nuaireeah General Hospital, Kingdom of Saudi Arabia.
[12]Nursing Specialist, Eradah - Mental Health Complex Aldammam, Kingdom of Saudi Arabia.
[13]Nursing Specialist, King Fahad Hospital in Medina, Madinah Health Cluster, Kingdom of Saudi Arabia.
[14]Specialist Medical Device, Hafer Albatin Cluster, Kingdom of Saudi Arabia.
[15]Nursing Technician, King Khalid Hospital in Najran, Najran Health Cluster, Kingdom of Saudi Arabia.

Abstract

Background

Sterilization forms the cornerstone of infection control in healthcare, eliminating all microbial life, including spores, from reusable critical and semicritical devices to prevent healthcare-associated infections (HAIs) like CLABSIs and VAPs, which affect 5-30% of patients and drive substantial morbidity, mortality, and costs. Technologies such as steam autoclaving, ethylene oxide (EtO), hydrogen peroxide plasma, and emerging plasma systems address multidrug-resistant organisms (MDROs) and biofilms per Spaulding classification, amid rising antimicrobial resistance.

Methods

This narrative review synthesized peer-reviewed evidence on sterilization devices' effectiveness, prioritization, and clinical impact, focusing on reusable devices in operating rooms, ICUs, and CSSDs. Data encompassed laboratory log reductions (>6-log10 for spores), clinical HAI reductions, cost-benefit analyses, outbreak case studies, and guidelines from CDC, WHO, and ISO standards, evaluating factors like cycle time, material compatibility, and environmental safety.

Results

Steam autoclaving excelled in efficacy and speed for surgical instruments, while low-temperature hydrogen peroxide and plasma suited heat-sensitive endoscopes, achieving sterility assurance levels of 10^{-6} and reducing HAIs by up to 70% via odds ratios of 0.30. Prioritization via risk assessment (e.g., FMEA) and precleaning lowered bioburden by 4-6 log10, with innovations like AI monitoring cutting errors by 40-50%; however, human factors and biofilms posed challenges, alongside EtO's toxicity.

Conclusions

Optimized sterilization prioritization enhances patient safety, curtails HAIs and costs (e.g., $642,010 savings per facility), and supports antimicrobial stewardship, urging adoption of eco-friendly, digital-integrated technologies and rigorous training.

Keywords: Sterilization devices, Infection control, Healthcare-associated infections, Spaulding classification, Steam autoclaving, Hydrogen peroxide plasma.

Introduction

Sterilization represents a cornerstone of infection control in healthcare settings, ensuring that reusable medical devices and instruments do not serve as vectors for pathogenic microorganisms, thereby safeguarding patient safety during invasive procedures and routine care. By achieving complete microbial elimination, including resilient bacterial spores, sterilization processes such as steam autoclaving, ethylene oxide gas, and hydrogen peroxide plasma mitigate the risk of healthcare-associated infections (HAIs), which impose substantial morbidity, mortality, and economic burdens on healthcare systems worldwide. Proper adherence to evidence-based sterilization protocols, guided by classifications like Spaulding's (critical, semicritical, noncritical items), is paramount, as deviations have repeatedly precipitated outbreaks, underscoring the non-negotiable imperative for rigorous cleaning prior to disinfection or sterilization in facilities handling high volumes of surgical and endoscopic interventions (Rutala & Weber, 2016).

Sterilization stands as an indispensable pillar in the multifaceted architecture of infection control within healthcare environments, where the proliferation of multidrug-resistant organisms (MDROs) and biofilms on device surfaces amplifies transmission risks during procedures involving sterile tissue or mucous membranes. In an era marked by escalating antimicrobial resistance, as highlighted by WHO priority pathogens, sterilization not only eradicates vegetative bacteria, viruses, fungi, mycobacteria, and spores but also addresses the limitations of disinfection methods, which may leave residual viable microbes capable of causing device-associated infections like central line-associated bloodstream infections (CLABSIs) or ventilator-associated pneumonias (VAPs). Healthcare facilities performing millions of inpatient surgeries and endoscopies annually rely on validated sterilization technologies such as low-temperature hydrogen peroxide systems or peracetic acid immersion, to maintain sterility assurance levels of 10^-6, preventing person-to-person pathogen transfer and reducing overall HAI incidence through standardized central sterile supply department (CSSD) protocols that integrate biological and chemical indicators for quality assurance (Garvey, 2023).

Healthcare-associated infections linked to medical devices constitute a predominant fraction of HAIs, accounting for 60-80% of bloodstream, urinary tract, and pneumonia-related cases, driven by pathogens such as ESKAPE organisms (Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, Enterobacter spp.) that form biofilms on indwelling catheters, endoscopes, and surgical instruments. Global data reveal HAI incidences ranging from 5-6.6% in hospitalized patients, with intensive care units (ICUs) exhibiting up to 30% infection rates, exacerbated by invasive devices like central venous catheters, urinary catheters, and duodenoscopes, where reprocessing failures due to complex designs with narrow lumens and elevator mechanisms facilitate persistence of carbapenem-resistant Enterobacteriaceae (CRE) and other MDROs. These infections prolong hospital stays by 5-11 days, elevate mortality risks (e.g., 4.5% unfavorable outcomes in affected patients), and underscore sterilization lapses as primary culprits, with outbreaks persisting despite guidelines, prompting calls for enhanced methods like double high-level disinfection or supplementary ethylene oxide sterilization (Garvey, 2023).

This review aims to systematically evaluate the effectiveness of sterilization devices in infection control, prioritizing modalities based on microbial kill efficacy, material compatibility, cycle times, and environmental safety amid regulatory shifts away from ethylene oxide due to carcinogenic concerns. It encompasses clinical impacts in diverse healthcare settings from operating rooms to ICUs analyzing HAI

reductions attributable to steam, gas plasma, and liquid chemical sterilants, while appraising prioritization frameworks informed by Spaulding's classification and real-world outbreak data. The scope delineates boundaries to peer-reviewed evidence on reusable critical and semicritical devices, excluding single-use items, and integrates emerging biological adjuncts like bacteriophages for biofilm disruption, offering evidence-based recommendations to optimize sterilization practices for minimizing device-associated HAIs (Haque et al., 2018).

Principles of Sterilization and Infection Control

Sterilization in healthcare settings refers to a comprehensive process that destroys or eliminates all forms of microbial life, including bacteria, viruses, fungi, and bacterial spores, ensuring that medical devices and instruments are safe for patient use without risk of infection transmission. The primary goals encompass achieving complete microbial inactivation to prevent healthcare-associated infections (HAIs), maintaining aseptic conditions during invasive procedures, and supporting evidence-based infection control protocols that align with regulatory standards from organizations like the CDC and WHO. This process is vital in high-risk environments such as operating rooms, intensive care units, and sterile processing departments, where improper sterilization can lead to outbreaks of resistant pathogens, prolonged patient stays, and increased mortality rates. By integrating physical methods like steam autoclaving, dry heat, or chemical agents such as ethylene oxide, sterilization not only targets vegetative cells but also resilient spores, distinguishing it as the gold standard for reusable critical devices(Rutala & Weber, 2015).

Sterilization differs fundamentally from disinfection and cleaning in scope, mechanism, and microbial kill efficacy, forming a hierarchical approach to reprocessing medical equipment. Cleaning involves the physical removal of visible soil, organic debris, and bioburden using detergents and water, serving as the essential first step to enable subsequent processes but not eliminating microorganisms. Disinfection reduces viable pathogens to safe levels low-level for non-critical items, intermediate for some semi-critical, and high-level targeting nearly all microbes except high numbers of spores yet falls short of guaranteed sterility. In contrast, sterilization achieves a validated 6-log reduction of spores, rendering items free of all viable life forms, which is non-negotiable for items breaching sterile barriers. These distinctions guide healthcare protocols, with cleaning always preceding disinfection or sterilization to prevent residue interference and ensure efficacy (Yoo, 2018).

The Spaulding classification system categorizes medical devices into critical, semi-critical, and non-critical based on their contact with patient tissues and associated infection risk, dictating the required reprocessing level. Critical devices, such as surgical instruments, implants, cardiac catheters, and biopsy forceps, penetrate sterile tissues or the vascular system and demand sterilization to eliminate all microbes, including spores, due to their high transmission potential. Semi-critical items, including endoscopes, laryngoscopes, and respiratory equipment, contact mucous membranes or non-intact skin, necessitating high-level disinfection that destroys vegetative bacteria, mycobacteria, fungi, viruses, and most spores, though sterilization is preferred when feasible. Non-critical devices like blood pressure cuffs, stethoscopes, and bedrails touch intact skin only, requiring low- to intermediate-level disinfection after cleaning, as skin acts as a natural barrier. Originating in 1957 and still foundational despite device complexities like flexible endoscopes with narrow lumens, this system ensures risk-stratified processing while adapting to modern innovations in materials and designs (Rowan et al., 2023).

Sterilization plays a pivotal role in preventing HAIs by breaking the chain of infection transmission through contaminated devices, significantly lowering morbidity, mortality, and healthcare costs in clinical settings. HAIs affect millions annually, with device-related infections contributing substantially; effective sterilization in central sterile supply departments has demonstrated pooled odds reductions of up to 70% in surgical site infections and overall nosocomial events via meta-analyses of protocol implementations. By ensuring devices meet sterility assurance levels (SAL of 10^-6), sterilization mitigates risks from pathogens like Clostridium difficile spores or multidrug-resistant bacteria, complementing hand hygiene and environmental controls. Studies highlight that lapses in sterilization monitoring lead to outbreaks,

underscoring its integration into quality audits, staff training, and surveillance systems for sustained impact. Robust sterilization practices thus enhance patient safety, reduce adverse events, and support antimicrobial stewardship amid rising resistance (Surabhi & Singh, 2025).

Types of Sterilization Devices and Technologies

Sterilization devices and technologies play a critical role in infection control within healthcare settings, with a wide range of methods available to ensure medical instruments and environments are free from viable microorganisms. The principal physical sterilization methods include steam autoclaves, dry heat, and various forms of radiation such as gamma, electron beam, and ultraviolet (UV) light. Steam autoclaving, the most widely used technique, relies on saturated steam under pressure to achieve sterilization and is highly effective for a broad array of medical devices, including surgical instruments, biopsy forceps, and implanted devices. Dry heat sterilization is suitable for items that cannot tolerate moisture, such as glassware and certain powders, and typically involves exposure to high temperatures (160–170°C) for extended periods. Radiation-based sterilization, including gamma and electron beam, is often employed for disposable medical supplies and packaging, as these methods do not generate significant heat and can penetrate packaging materials to sterilize contents without compromising device integrity (Rutala & Weber, 2016).

Chemical sterilization encompasses the use of ethylene oxide (EtO) gas, vaporized hydrogen peroxide (VHP), and peracetic acid, each with distinct advantages and applications. Ethylene oxide gas is a low-temperature process that is highly effective for sterilizing heat- and moisture-sensitive devices such as pacemakers, catheters, and ventilators. However, it requires lengthy aeration times to remove toxic residues and poses safety concerns due to its carcinogenicity. Vaporized hydrogen peroxide and peracetic acid are frequently used in low-temperature sterilization systems, particularly for endoscopes and other delicate instruments, offering rapid cycles and reduced toxicity compared to EtO. These methods are often favored in settings where turnaround time is critical and safety is a priority (Shintani, 2017).

Emerging and advanced sterilization technologies are rapidly evolving to address limitations of traditional methods and improve efficiency, safety, and environmental impact. Plasma sterilization, which uses hydrogen peroxide plasma or other reactive species, is increasingly used for sterilizing intricate and heat-sensitive instruments such as endoscopes, with the advantage of shorter processing times and lower toxicity compared to EtO. Electron beam sterilization, another advanced technique, provides rapid, cold sterilization and is suitable for disposable devices and packaging. Additionally, innovations such as nano-silver and ozone-based technologies are being explored for their potential to provide effective, environmentally friendly alternatives to conventional sterilization, especially for surface and environmental disinfection (Rutala et al., 2023).

When comparing sterilization methods, efficacy, safety, cost, and processing time are key considerations for healthcare facilities. Steam sterilization consistently demonstrates the highest efficacy and shortest processing time, making it the preferred choice for most reusable surgical instruments. Ethylene oxide, while effective for a broader range of devices, has the longest cycle time and highest safety risks due to its toxic and carcinogenic properties. Vaporized hydrogen peroxide and plasma sterilization offer a balance of rapid cycles, safety, and moderate cost, but are generally more expensive per cycle than steam or EtO. Radiation-based methods are highly effective and efficient for large-scale sterilization of disposables but require specialized facilities and are less suitable for routine in-house use. The choice of sterilization method must be tailored to the device type, facility resources, and infection control priorities, balancing effectiveness with practicality and safety (Maamari et al., 2016).

Effectiveness of Sterilization Devices

Sterilization devices achieve microbiological efficacy through substantial log reductions in pathogens, including resistant bacteria, bacterial spores, and viruses, with high-performing systems like washer-

disinfectors and steam autoclaves routinely demonstrating greater than 7-log10 reductions in viable microorganisms on contaminated surgical instruments, even without enzymatic cleaners. Studies on ultraviolet-C (UV-C) systems and pulsed xenon UV (PX-UV) have shown over 3-log10 reductions in vegetative bacteria such as MRSA and VRE, alongside 2.4-log10 or higher reductions in C. difficile spores, particularly when surfaces are in direct line-of-sight, though efficacy diminishes in shadowed areas. Emerging technologies, including ozonized water and compressive heating vapor systems, report log10 reductions ranging from 1.72-2.40 to over 6-log10 against a broad spectrum of pathogens, underscoring their role in eliminating spores like Geobacillus stearothermophilus and viruses in healthcare settings (Lee et al., 2014).

Evidence from clinical and laboratory studies highlights the robust effectiveness of sterilization devices against key healthcare-associated pathogens like MRSA and C. difficile, where machine washer-disinfectors reduce MRSA by factors exceeding 1:100,000 prior to final sterilization, and container-based steam processes achieve over 1:10,000,000 reductions, consistently killing 10^5 C. difficile and G. stearothermophilus spores even under suboptimal conditions. Whole-room disinfection devices, such as hydrogen peroxide vapor (aHP) and UV systems, have demonstrated up to 100% reduction in MRSA contamination and significant decreases in hospital-wide MRSA infection rates by 41.1% when combined with manual cleaning. Targeted enhanced terminal disinfection using UV alongside standard chemical methods further lowers acquisition of multidrug-resistant organisms, including C. difficile, validating these devices' clinical impact in reducing pathogen transmission on medical instruments and surfaces (Donskey et al., 2014).

Biofilms significantly compromise sterilization effectiveness by forming protective matrices on medical devices, rendering pathogens like Staphylococcus aureus, Pseudomonas aeruginosa, and Enterococcus species up to 15-fold more resistant to antimicrobials and biocides, with biofilm maturity and thickness delaying disinfectant penetration and reducing log reductions to below required thresholds even at doubled concentrations. On stainless steel surfaces common in healthcare equipment, bacterial biofilms of Listeria innocua, Pseudomonas putida, and Staphylococcus hominis resist standard disinfectants, achieving only partial 5-log reductions in select cases like Micrococcus luteus, while persister cells and quorum-sensing mechanisms further enhance intrinsic resistance. Novel enzymatic cleaners and cold atmospheric plasma methods address this by removing 90-95% of S. aureus and P. aeruginosa biofilms from endoscopes, highlighting the need for biofilm-disrupting adjuncts to restore sterilization efficacy against device-associated infections (Królasik et al., 2010).

Sterilization failure and resultant contamination risks arise primarily from human factors like inadequate staff training, protocol non-compliance, and improper equipment use, as seen in high failure rates (up to 7.4%) in primary and secondary hospitals where autoclave pressure inconsistencies and premature unloading without cooling periods lead to incomplete spore inactivation. Equipment malfunctions, insufficient maintenance, and overlooked biological indicator verification exacerbate risks, particularly for critical devices like duodenoscopes harboring MDR pathogens such as CRE, while system failures like unactivated steam sterilizers have distributed non-sterile instrument packs, amplifying person-to-person transmission potential. Mitigation through standardized processes, such as HFMEA-identified checks for scanning, verification, and holding times, alongside evolved device designs under Spaulding's classification, is essential to minimize these failures and ensure infection control in clinical settings (Garvey, 2023).

Prioritization of Sterilization Processes in Clinical Settings

The prioritization of sterilization processes in clinical settings hinges on the Spaulding classification system, which categorizes medical devices into critical, semi-critical, and non-critical based on their risk of infection transmission during patient contact. Critical devices, such as surgical instruments that penetrate sterile tissue or the vascular system, demand full sterilization to eradicate all microorganisms including spores, ensuring a sterility assurance level of 10^{-6}, while semi-critical devices like endoscopes that

contact mucous membranes or non-intact skin typically require high-level disinfection but may necessitate sterilization in high-risk scenarios to mitigate emerging threats from multidrug-resistant organisms. This rationale stems from the degree of tissue invasion and potential for cross-contamination, with prioritization elevating critical items to steam autoclaving or low-temperature methods like hydrogen peroxide gas plasma when heat-sensitive, thereby optimizing resource allocation in busy healthcare environments where immediate availability of sterile instruments is paramount(Rowan et al., 2023).

Risk assessment in device reprocessing forms the cornerstone of sterilization prioritization, employing tools like Failure Mode and Effects Analysis (FMEA) to identify high-risk failure points such as inadequate brushing during cleaning or improper high-level disinfection, which can lead to unacceptable risk priority numbers exceeding 100 and compromise patient safety. These assessments evaluate factors including device complexity, bioburden levels, patient vulnerability, and environmental controls, directing resources toward critical devices in high-acuity areas while allowing semi-critical items to undergo validated disinfection protocols if sterilization capacity is limited. Implications include enhanced traceability systems, staff training, and infrastructure upgrades to address organizational deficiencies, ultimately reducing healthcare-associated infections by aligning reprocessing rigor with procedural invasiveness and microbial resistance patterns observed in modern pathogens (Redin et al., 2025).

Guidelines and protocols for sterilization vary across healthcare environments to reflect procedural demands and patient risks, with operating rooms mandating steam sterilization for all critical instruments like scalpels and implants due to direct sterile tissue entry, supported by centralized sterile processing departments equipped with biological and chemical indicators for cycle validation. In dental clinics, protocols emphasize rapid turnaround autoclaving for critical handpieces and burs alongside high-level disinfection for semi-critical mirrors and probes, incorporating FDA-cleared cycles and bi-monthly biological monitoring to comply with standards like those from the Pharmacopoeia of the United Mexican States. Intensive care units (ICUs) prioritize portable sterilization for semicritical respiratory equipment and ventilators, often using hydrogen peroxide vapor or peracetic acid immersion for heat-sensitive items, with protocols integrating Spaulding reclassification proposals for high-risk endoscopes to shift from disinfection to sterilization amid outbreaks of resistant bacteria (Kothekar & Kulkarni, 2020).

The role of cleaning and pre-sterilization steps cannot be overstated in process prioritization, as thorough precleaning reduces bioburden by 4-6 log_{10} through mechanical removal of organic debris like blood and proteins using enzymatic detergents, ultrasonic cleaners, or brushing, which is essential before disinfection or sterilization to prevent shielding of microbes and ensure efficacy of subsequent sterilants. These steps dictate prioritization by identifying devices amenable to full sterilization versus those needing only high-level disinfection, with forced-air drying post-rinsing minimizing recontamination and neutral pH enzymatic cleaners preserving device integrity for delicate semi-critical items like flexible endoscopes. In prioritization frameworks, inadequate precleaning elevates even low-risk devices to critical status, prompting protocols that sequence cleaning immediately post-use, followed by packaging and sterilization in designated zones to maintain sterility margins and support just-in-time availability in clinical workflows (Mohapatra, 2017).

Clinical Impact of Effective Sterilization

Effective sterilization of medical devices significantly reduces healthcare-associated infection (HAI) rates by eliminating multi-drug-resistant pathogens and biofilms that persist on reusable equipment like endoscopes and surgical instruments, directly lowering morbidity and mortality in clinical settings. Studies demonstrate that robust sterilization protocols, including steam autoclaving, vaporized hydrogen peroxide, and ethylene oxide, achieve a sterility assurance level (SAL) of 10^{-6}, preventing transmission of ESKAPE pathogens such as Pseudomonas aeruginosa and Klebsiella pneumoniae, which are commonly linked to ventilator-associated pneumonia, catheter-related urinary tract infections, and surgical site infections. In hospital environments, adherence to these methods has shown consistent reductions in HAI incidence, with central sterile supply department management protocols yielding pooled odds ratios of 0.30

for HAIs and 0.15 for adverse events across multiple studies, underscoring the direct clinical efficacy in diverse healthcare facilities. This impact extends to intensive care units where up to 30% of patients acquire HAIs, highlighting sterilization as a cornerstone intervention for patient protection (Garvey, 2023).

Case studies illustrate profound infection control improvements following enhanced sterilization implementation, such as a real-time evaluation of sterilization failure risks where machine washer/disinfectors reduced MRSA by 1:100,000 and subsequent sterilization eliminated over 10^7 C. difficile spores, rendering transmission risk negligible at 1 in 100 trillion. In another instance, nationwide assessments in primary and secondary care hospitals revealed that 71% of steam sterilization cycles were ineffective against biological indicators, prompting protocol refinements that boosted efficacy and curtailed nosocomial outbreaks. Enhanced cleaning and disinfection interventions, like the CLEEN study, demonstrated reduced HAI proportions through thorough equipment decontamination, with fluorescence marker audits confirming improved surface sterilization compliance post-implementation. These examples, including PDCA cycle applications in sterile supply centers, not only lowered incision infection rates and pathogen detection but also elevated staff knowledge and endoscope disinfection rates, proving scalable sterilization upgrades transform infection trajectories in real-world clinical practice (Browne et al., 2023).

Cost-benefit analyses consistently affirm that investing in effective sterilization yields substantial savings by curtailing HAIs, shortening hospital stays, and minimizing antibiotic utilization amid rising antimicrobial resistance. Economic modeling of low-temperature sterilization for endoscopes showed savings from reduced repairs outweighing costs, with an 81% probability of achieving a 6% internal rate of return over 10 years in large facilities. Simulations of C. difficile control interventions identified daily sporicidal cleaning and sterilization enhancements as dominant strategies, saving $358,268 annually while preserving 36.8 quality-adjusted life-years per 200-bed hospital by averting infections and associated treatments. Further, enhanced disinfection of shared equipment cut HAIs from 130 to 100 per 1000 patients, generating $642,010 in net savings with a 90.5% cost-saving probability, factoring in averted hospital stays and antibiotic courses. These analyses emphasize prioritization of high-impact sterilization over less effective measures, optimizing resource allocation while curbing the $31,979–$64,926 per life-year cost of suboptimal practices (McCreanor & Graves, 2017).

Patient safety and public health implications of effective sterilization are profound, safeguarding vulnerable populations from MDR fungal and bacterial threats like Candida auris and CRE, which evade conventional antimicrobials and elevate sepsis risks. By mitigating device-related HAIs, which account for 80% of urinary tract infections, bloodstream infections, and pneumonias in the US (1.7 million cases, 99,000 deaths yearly), sterilization upholds public health security and aligns with WHO priorities for critical pathogens. Breaches in sterilization, often due to complex device geometries like duodenoscope elevators, have triggered outbreaks even under guideline compliance, reinforcing the need for advanced modalities such as vaporized peracetic acid or phage-based innovations to eliminate prions, endotoxins, and biofilms. Ultimately, prioritizing sterilization not only enhances individual patient outcomes reducing post-discharge surgical site infections by up to 60% but also curtails AMR proliferation, supporting sustainable healthcare systems globally (Patel & Jain, 2020).

Challenges and Limitations in Sterilization

Compliance issues and human factors represent significant barriers to achieving reliable sterilization outcomes in healthcare settings, where deviations from protocols often stem from cognitive overload, inadequate training, and workflow inefficiencies among sterile processing personnel. Studies reveal that breaches in cleaning, packaging, and loading procedures frequently occur due to human error, exacerbated by staffing shortages, high workload during peak surgical periods, and insufficient awareness of traceability systems, leading to undetected sterilization failures and increased risk of healthcare-associated infections. For instance, lapses in verifying exchange slips against information systems or failing to cool sterilized items adequately result in wet packages and non-sterilized items, undermining the entire process despite available technological safeguards. These challenges persist across various facilities, with suboptimal

adherence to guidelines documented in multiple international audits, highlighting the need for human factors engineering interventions like refined standard operating procedures and performance-based incentives to enhance compliance (Pennathur & Herwaldt, 2017).

Current sterilization technologies face substantial limitations when processing complex instruments such as endoscopes and implants, primarily due to their intricate luminal structures, narrow channels, and heat-sensitive materials that hinder thorough cleaning and microbial elimination. Endoscopes, in particular, retain high bioburden levels post-cleaning, with proteins and organic residues persisting in bends and elevators despite high-level disinfection, as manual brushing and automated washers often fail to reach all surfaces effectively. Implants pose additional challenges with their porous or assembled designs, where steam penetration is inconsistent, and low-temperature methods like ethylene oxide carry residual gas risks without guaranteeing prion inactivation. These shortcomings contribute to outbreaks linked to inadequately reprocessed devices, as quality control methods for channel cleanliness remain underdeveloped, amplifying cross-infection potential even under current guidelines (Madureira & Oliveira, 2022).

Environmental and safety concerns further complicate sterilization practices, as chemical agents like ethylene oxide, glutaraldehyde, and quaternary ammonium compounds leave residues that pose toxicity risks to patients, staff, and ecosystems. Ethylene oxide, valued for penetrating heat-labile devices, is a known carcinogen linked to respiratory issues and cancer in exposed workers, prompting stricter emissions regulations that disrupt supply chains and inflate costs for facilities. Device damage from corrosive disinfectants and improper handling accelerates equipment wear, while wastewater discharge introduces disinfection by-products harmful to aquatic life and microbial communities in sewage treatment plants. These issues underscore the tension between efficacy and sustainability, with persistent chemical buildup in soil and water exacerbating ecotoxicity and bioaccumulation in vulnerable populations (Ng et al., 2025).

Emerging threats from multidrug-resistant organisms and biofilms intensify the limitations of sterilization, as these microbial communities embed deeply into device surfaces, exhibiting tolerance to standard disinfectants far beyond planktonic cells. Biofilms on endoscopes and implants shield pathogens like MRSA and carbapenem-resistant Enterobacteriaceae, rendering conventional steam, gas, or chemical methods insufficient due to matrix barriers that slow penetration and promote horizontal gene transfer of resistance genes. In hospital settings, these structures drive persistent healthcare-associated infections, particularly in high-touch environments, where artificial sweat and organic soils foster rapid regrowth post-reprocessing. Addressing this crisis demands novel antibiofilm strategies, yet current protocols lag, perpetuating MDR outbreaks amid rising antibiotic stewardship failures (Yahya et al., 2025).

Monitoring and Quality Assurance of Sterilization Processes

Monitoring and quality assurance of sterilization processes represent a cornerstone of infection control in healthcare settings, ensuring that medical devices are reliably free from viable microorganisms to prevent healthcare-associated infections. This multifaceted approach integrates physical parameters such as temperature, pressure, and time with chemical and biological indicators to validate process efficacy, detect deviations, and maintain compliance with international standards like ISO 17665 and ISO 11140. Comprehensive monitoring not only confirms the lethality of each cycle but also supports ongoing process improvement through data-driven audits and failure investigations, ultimately safeguarding patient safety across diverse clinical environments from operating rooms to central sterile supply departments (Lagos-Palomino et al., 2023).

Biological indicators, typically containing highly resistant bacterial spores such as Geobacillus stearothermophilus for steam sterilization, serve as the gold standard for verifying sterilization lethality by directly assessing microbial inactivation under real process conditions. These indicators are incorporated into process challenge devices (PCDs) placed in the most challenging locations within loads, such as lumens or wrapped packs, to simulate worst-case scenarios and validate that all critical parameters time, temperature, and sterilant penetration have been met, as required by standards like ISO 11138 and

ANSI/AAMI ST79. Process validation using biological indicators occurs during initial installation, after repairs, and periodically for routine assurance, with rapid-read variants providing results in 20-25 minutes compared to traditional 24-48 hour incubation, enabling faster load release while confirming a minimum 6-log reduction in spore viability (Jabbari et al., 2012).

In low-temperature hydrogen peroxide gas plasma sterilization, particularly for heat-sensitive luminal devices like endoscopes, biological PCDs tailored to lumen geometry outperform standard indicators by accounting for limited sterilant penetrability, with studies showing lower qualification rates that highlight true process vulnerabilities and necessitate device-specific monitoring protocols. Validation extends to bioburden assessment and half-cycle testing for novel processes, ensuring reproducibility across production lots, while integrating biological data with physical and chemical monitors provides parametric release confidence, reducing reliance on quarantine periods. This rigorous validation framework not only detects failures like inadequate steam quality or air removal but also quantifies process robustness through D-values and survivor curves, informing cycle optimization and regulatory submissions (Wang et al., 2021).

Routine monitoring encompasses daily physical verification of cycle parameters via printouts, gauges, and digital logs, augmented by chemical indicators (especially Class 5 or 6 emulating types) in every pack or load to confirm exposure to specified conditions like 134°C for 3.5 minutes in saturated steam. Biological indicators are mandated weekly or daily in high-volume settings for sterilizer efficacy checks using PCDs, with immediate incubation and documentation of results, positive controls, and any growth prompting load recalls and root-cause analyses such as steam quality testing for non-condensables. Auditing practices involve periodic reviews of device history records, compliance with standard operating procedures, and external proficiency testing, ensuring traceability from loading to storage while addressing operator errors, equipment calibration drifts, or packaging failures that could compromise sterility (Ling et al., 2018).

Multisociety guidelines emphasize combining all three monitoring modalities for load release, with Type 5 chemical indicators and biologicals mandatory for implants, alongside quarterly process audits that include staff competency assessments and environmental controls to minimize recontamination risks. In resource-limited settings, simplified protocols prioritize biological testing frequencies based on usage volume, while electronic record-keeping facilitates trend analysis for predictive maintenance, reducing unplanned downtime by up to 30% in audited facilities. These practices align with CDC, AAMI, and WHO recommendations, fostering a culture of continuous quality improvement where audit findings drive targeted interventions like retraining or equipment upgrades (Basu, 2019).

Recent innovations integrate IoT-enabled sensors for real-time parameter tracking, providing cloud-based dashboards that alert operators to deviations in temperature, humidity, or sterilant concentration before cycle completion, enhancing parametric release for vaporized hydrogen peroxide systems. AI-powered predictive analytics analyze historical data to forecast failures, optimize load configurations, and automate documentation, while rapid enzymatic indicators detect spore inactivation in under 15 minutes via fluorescence, bridging the gap between chemical speed and biological accuracy for high-throughput environments. Blockchain traceability ensures tamper-proof audit trails from manufacturer to point-of-use, supporting global regulatory harmonization (Karimi Estahbanati, 2023).

Smart sterilization containers with embedded RFID and electromagnetic seals monitor barrier integrity post-process, validated to withstand autoclave extremes without compromising electronics, while multimodal biological indicators combine spore strips with digital readouts for 3-hour results in ethylene oxide cycles. Advances in low-temperature plasma monitoring employ spectroscopic sensors to quantify hydrogen peroxide residuals and plasma density, addressing lumen-specific challenges in endoscopy reprocessing per updated Z314 standards. These technologies reduce human error by 40-50%, lower environmental footprints through efficient cycles, and enable remote auditing, positioning sterilization as a proactive rather than reactive component of infection prevention (Rutala et al., 2023).

Future Directions and Innovations

The landscape of sterilization in infection control is evolving rapidly with novel agents and technologies under research, including advanced plasma systems, pulsed ultraviolet light, and hydrogen peroxide gas plasma, which offer low-temperature, residue-free alternatives to traditional methods like autoclaving, particularly suited for heat-sensitive medical devices in healthcare settings. Dry hydrogen peroxide vapor combined with UV-C radiation has shown high efficacy in prototype mobile sterilization stations, achieving complete microbial inactivation without generating hazardous waste, positioning it as a promising tool for point-of-care applications in clinical environments. Pulsed light technology delivers rapid, broad-spectrum disinfection on surfaces, leaving no residues and outperforming slower heat or chemical methods in speed and environmental safety, while cold plasma generates reactive species to destroy pathogens without damaging instruments. Vaporized hydrogen peroxide and hydrogen peroxide-ozone combinations further enhance compatibility with complex devices like endoscopes, addressing limitations of steam sterilization on moisture-sensitive materials. These innovations prioritize effectiveness against resistant pathogens, including spores and biofilms, potentially reducing healthcare-associated infections through faster cycle times and broader material compatibility (Bharti et al., 2022).

Integration of sterilization processes into digital healthcare ecosystems leverages smart tracking systems, IoT-enabled monitoring, and AI-driven analytics to ensure compliance, traceability, and predictive maintenance in central sterile supply departments (CSSDs), transforming manual workflows into automated, error-free operations. Unique device identification (UDI) barcode systems for surgical instruments enable real-time cycle logging, zero-error identification across thousands of sets, and digital elimination of paper records, saving resources while linking packages to patient records for enhanced accountability. RFID and barcode instrument tracking in hospitals optimizes operating room efficiency, curbs losses, and verifies sterilization compliance through analytics, while electronic alerts and pictorial packing lists in CSSDs reduce resterilization needs by nearly 99% and damage to zero. AI-powered solutions adjust parameters in real-time, minimizing energy use and human error, allowing technicians to focus on quality assurance amid rising procedural volumes. These digital advancements foster a "smart hospital" infrastructure, where sterilization data integrates with electronic health records for proactive infection prevention (J.-H. Liu et al., 2025).

Prospects for biologics like bacteriophages in sterilization hold transformative potential as targeted, species-specific antimicrobials against multidrug-resistant pathogens on medical devices, offering prophylactic and metaphylactic control where chemical methods falter. Phages, endolysins, and antimicrobial peptides effectively combat WHO priority ESKAPE bacteria on biomaterials, with combinations like chlorhexidine-gluconate and phages demonstrating synergistic surface disinfection on contaminated needles, significantly outperforming individual agents. In phage therapy, lysates undergo advanced filtration for sterility, excluding endotoxins and debris while concentrating therapeutic particles, supporting clinical use against MDR infections with reported 77% improvement rates despite standardization challenges. Phages inactivate biofilms and persist longer than broad-spectrum agents, addressing device-associated infections in urology and orthopedics, with regulatory pathways like FDA's emergency IND facilitating trials. Their precision minimizes microbiome disruption, heralding a shift from indiscriminate sterilization to biologic precision medicine (Y. Liu et al., 2023).

Sustainability drives eco-friendly sterilization options, emphasizing reduced energy, water, and waste through reusable devices, plasma methods, and biodegradable materials, countering the environmental footprint of single-use plastics and high-resource autoclaving in healthcare. Reusable products cut greenhouse gas emissions by 13-100%, waste by 99%, and water use in some cases, though hybrid models balance increased cleaning demands with overall ecological superiority over disposables. Plasma sterilization at low temperatures avoids pollution, ideal for plastics, while eco-alternatives like cellulose pouches and non-toxic tapes minimize chemical leachates in waste streams. Autoclaving for waste achieves low CO2 equivalents (569 kg/t), outperforming incineration, and IoT optimizes cycles to conserve resources without efficacy loss. These green innovations align infection control with net-zero goals, promoting durable, recyclable infrastructure resilient to multiple cycles (Tozsin et al., 2025).

HEPA filtration in infection control

High-efficiency particulate air (HEPA) filters are mechanical filters that remove at least 99.97% of particles with an aerodynamic diameter of ≥0.3 μm, capturing most droplet nuclei and many bioaerosols relevant to healthcare-associated infections (HAIs). In contrast to device sterilization technologies that target instruments and surfaces, HEPA filtration acts on room air and ventilation systems to reduce airborne pathogen loads, complementing standard precautions, environmental cleaning, and sterilization of critical and semicritical devices. Airborne infection isolation rooms (AIIRs), operating rooms, and high-risk units such as hematology–oncology and transplant wards routinely incorporate HEPA filters in supply or exhaust ducts to protect immunocompromised patients from fungal spores, notably Aspergillus, and to contain airborne pathogens such as Mycobacterium tuberculosis and SARS-CoV-2 (Brady et al., 2025).

From a technical standpoint, HEPA media are composed of dense mats of randomly arranged glass microfibers that remove particles via interception, impaction, and diffusion, with efficiency actually increasing for particles smaller than 0.3 μm because of Brownian motion–driven diffusion. Guidance for airborne isolation specifies that HEPA filtration should be combined with adequate air changes per hour (ACH), usually a minimum of 12 ACH in AIIRs, to ensure sufficient dilution and removal of infectious aerosols. In this context, HEPA-based air cleaners or duct-mounted units are sized in terms of "equivalent ACH" they add to a space, allowing facilities with suboptimal building ventilation to reach guideline-recommended ventilation rates without complete HVAC replacement. Together, high capture efficiency and adequate airflow turnover underpin the role of HEPA filters as an engineering control that reduces the probability of exposure, especially during aerosol-generating procedures or in crowded clinical areas (Brady et al., 2025).

Experimental and clinical studies show that HEPA filtration significantly reduces airborne concentrations of respiratory viruses, fungi, and bacteria in healthcare environments. In controlled chamber experiments, air cleaners equipped with HEPA filters removed infectious SARS-CoV-2 in a time- and ventilation volume–dependent manner, achieving virus capture ratios above 99.97% after multiple chamber air volumes had passed through the filter. Observational hospital data similarly link HEPA filtration to lower infection risk: in high-risk hematology units, the introduction of HEPA-filtered rooms and corridors has been associated with marked reductions in invasive aspergillosis incidence, with one systematic review reporting nearly halved incidence ratios and negligible filtration costs compared with the savings from avoided infections. More recently, a review of interventions to reduce infectious aerosols in healthcare concluded that mechanical filtration, particularly HEPA-based systems, was the most consistently effective environmental control across multiple studies (Okokon et al., 2025).

Evidence from perioperative areas reinforces the impact of HEPA filters on airborne bioburden and potential surgical site infections (SSIs). Studies of operating rooms using HEPA-filtered laminar or ultra-clean airflow systems demonstrate significant reductions in viable airborne bacteria and particle counts, with resulting decreases in deep joint infection risk in orthopaedic theatres when coupled with strict aseptic technique. In one hospital study, installing HEPA filters over ventilation grilles between an operating theatre and a recovery area was identified as the most effective solution to prevent recirculation of potentially contaminated air and mitigate nosocomial spread of SARS-CoV-2. These findings align with broader evidence that whole-room air cleaning using HEPA units, when used as an adjunct to manual cleaning and sterilization of instruments, improves overall environmental hygiene and can contribute to lower HAI rates (Dolcini et al., 2025).

In airborne infection isolation rooms, HEPA filtration is integral to both source containment and environmental protection. Standard design guidance recommends that exhaust air from AIIRs be discharged outdoors, often after passage through terminal HEPA filters located close to the exhaust point to minimize lengths of contaminated ductwork. International guidelines further recommend HEPA filters on supply air for certain isolation and protective environments, ensuring that incoming air is free of fungal spores and other particulates that could harm severely immunocompromised patients. Where existing HVAC systems

cannot be easily modified, portable HEPA filtration units deployed within patient rooms or corridors can create negative-pressure zones and achieve the equivalent of 10–12 ACH, approximating the performance of purpose-built AIIRs when correctly positioned and ducted (Fennelly et al., 2023).

During respiratory virus surges and pandemics, expedient isolation strategies increasingly rely on portable HEPA units to convert standard rooms into temporary AIIRs or to support cohort wards. Guidance for such temporary solutions emphasizes selection of devices with adjustable airflow, validated HEPA filters, and performance leak testing, along with configuration that draws air from the patient zone across staff work areas and out through HEPA-filtered exhaust to minimize staff exposure. These deployments can be rapidly scaled, are relatively low-cost compared with structural renovations, and offer measurable reductions in airborne particle counts and viral RNA, although their effectiveness depends on appropriate room sealing, device maintenance, and integration with broader infection prevention measures such as masking, hand hygiene, and environmental cleaning (Fernández de Mera et al., 2022).

Although HEPA filtration is highly effective for removing particulate bioaerosols, it does not inactivate microorganisms and offers no protection against gaseous hazards, so it must be integrated with upstream controls such as source control, device sterilization, and surface disinfection. Filters progressively load with dust and biological debris, which can increase pressure drops and reduce airflow; consequently, scheduled inspection and replacement based on manufacturer specifications and monitored pressure differentials are essential to maintain performance. Poorly maintained or incorrectly installed HEPA filters, including bypass leaks around frames or in housings, can create a false sense of security and allow unfiltered air to short-circuit the system, underscoring the need for commissioning tests and periodic integrity checks such as aerosol challenge or leak testing in high-risk applications (Pirkle et al., 2021).

Noise, drafts, and space requirements are practical limitations in patient rooms, especially when using portable units, and staff must be trained to avoid blocking intakes or exhausts with equipment or furniture. Moreover, filtration alone cannot compensate for inadequate air mixing or dead zones; optimal layouts place HEPA exhaust near the patient's head or source of aerosol and supply air behind or above staff whenever possible to ensure that clean air flows from staff to patient to exhaust. Despite these constraints, regulatory and professional bodies increasingly recommend upgrading or supplementing hospital ventilation with HEPA filtration either centrally or via local devices as part of a layered strategy to prevent device- and airborne transmission alongside sterilization, environmental cleaning, and antimicrobial stewardship (Pirkle et al., 2021).

Conclusion

Sterilization devices form the bedrock of infection control in healthcare, delivering validated microbial elimination to curb HAIs from critical and semicritical devices amid rising MDROs and biofilms. Steam autoclaving, low-temperature hydrogen peroxide plasma, and emerging plasma technologies excel in efficacy, though prioritization per Spaulding classification, rigorous precleaning, and quality assurance with biological indicators remain essential for clinical impact, including reduced morbidity, shorter stays, and cost savings. Future innovations in AI monitoring, phage biologics, and sustainable methods promise enhanced safety, compliance, and environmental stewardship, urging facilities to adopt evidence-based protocols for optimal patient outcomes.

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